Complete Summary

GUIDELINE TITLE

Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation.

BIBLIOGRAPHIC SOURCE(S)

University of Newcastle upon Tyne, Center for Health Services Research, University of York, Centre for Health Economics, Medicines Evaluation Group. Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation. Newcastle upon Tyne (UK): University of Newcastle upon Tyne, Centre for Health Services Research; 2001 Apr. 115 p. [289 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Myocardial infarction

GUIDELINE CATEGORY

Management
Prevention
Rehabilitation
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice

Internal Medicine
Nursing
Physical Medicine and Rehabilitation

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations to guide health care professionals in the appropriate primary care management of secondary prophylaxis for patients who have previously experienced a myocardial infarction (MI)
- To examine and present the evidence concerning the appropriate sequencing of drugs and other interventions for secondary prophylaxis in patients with a prior myocardial infarction, and to identify whether this differs according to prognostic risk factors (principally heart failure)

TARGET POPULATION

Patients who have experienced a myocardial infarction

INTERVENTIONS AND PRACTICES CONSIDERED

Drug Treatment (Including Time of Initiation, Sequencing, Monitoring, and Treatment Duration)

1. For patients with prior myocardial infarction who do not have heart failure, use of:
    - Beta blockers (e.g., atenolol, labetolol, metoprolol [Betaloc], oxprenolol, practolol, propranolol, timolol, carvedilol, xamoterol, pindolol, acebutolol, alprenolol, sotalol, bisoprolol [Emcor/Monocor])
    - Antiplatelet drugs (e.g., aspirin, sulphinpyrazone, dipyridamole, clopidogrel)
    - Statins (e.g., pravastatin [Lipostat], simvastatin [Zocor]),
    - Angiotensin-converting enzyme (ACE) inhibitors (e.g., fosinopril, benazepril, spirapril, cilazapril, lisinopril, quinapril, captopril, ramipril [Triace], enalapril)
    - Calcium channel blockers (e.g., nisoldipine, nifedipine, diltiazem, verapamil); nitrates; and potassium channel activators (nicorandil) as second-line therapy or for the management of specific symptoms and risk factors
    - Monitoring treatment through serum cholesterol (patients receiving statins) and renal function (patients on angiotensin-converting enzyme inhibitors)
2. For patients with prior myocardial infarction who have diabetes:

- Insulin glucose infusion, followed by subcutaneous insulin therapy

3. For patients with prior myocardial infarction and heart failure:
    - Angiotensin-converting enzyme inhibitors, beta blockers, antiplatelet drugs (aspirin), spironolactone, loop diuretic (Note: statins are also considered for this group, although no evidence is available)
    - Monitoring treatment through renal function (patients receiving angiotensin-converting enzyme inhibitors) and serum potassium (patients on spironolactone)

Non-drug Treatment

1. Cardiac rehabilitation, including exercise
2. Dietary manipulation including use of a Mediterranean-type diet

MAJOR OUTCOMES CONSIDERED

- Fatal and non-fatal re-infarctions
- Non-fatal stroke
- Electrocardiographic signs
- Death/all-cause mortality
- Hospitalization

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The aim of this review was to identify and synthesise relevant published and unpublished evidence to allow recommendations to be evidence-based wherever possible. The search was carried out using the electronic databases MEDLINE, EMBASE, SIGLE and the Cochrane Controlled Trial Register, attempting to locate systematic reviews and meta-analyses, randomised trials, quality of life studies and economic studies using a combination of subject heading and free text searches. The authors made extensive use of high quality recent review articles and bibliographies, as well as contact with subject area experts. New searches were concentrated in areas of importance to the guideline development process, for which existing systematic reviews were unable to provide valid or up to date answers. The expert knowledge and experience of group members also backed up the search strategy.

Electronic searches used an optimally sensitive search strategy based on a combination of text and index terms to locate randomised trials of treatments relevant to the guideline. Where data necessary for analyses, or which described the context of a trial, were not reported, guideline developers wrote to authors and sponsoring agencies (predominantly the pharmaceutical industry), reminding non-responders after approximately one month.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence categories were adapted from the U.S. Agency for Health Care Policy and Research Classification (AHCPR, 1992; now known as the Agency for Healthcare Research and Quality). This categorisation is most appropriate to questions of causal relationships. Potentially, six categories are available:

- Ia: evidence from meta-analysis of randomised controlled trials
- Ib: evidence from at least one randomised controlled trial
- IIa: evidence from at least one controlled study without randomisation
- IIb: evidence from at least one other type of quasi-experimental study
- III: evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-controlled studies
- IV: evidence from expert committee report or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once clinical questions had been identified, the guidelines development group assessed the quality of relevant studies retrieved and their ability to provide valid answers. Assessment of study quality concentrated on questions of internal validity (the extent to which the study measured what it intended to measure), external validity (the extent to which study findings could be generalised to other treatment settings) and construct validity (the extent to which measurement corresponded to theoretical understanding of a disease). The specific dimensions of quality examined in each study were as follows:

- Appropriateness of inclusion and exclusion criteria
- Concealment of allocation
- Blinding of patients
- Blinding of health professionals
- Objective/blind method of data collection
- Valid/blind method of data analysis
- Completeness and length of follow up
- Appropriateness of outcome measures
- Statistical power of results

Once individual papers had been checked for methodological rigour and clinical significance, the information was synthesised. Pharmaceutical studies often have an insufficient sample size to identify significant outcomes with confidence, so where appropriate, the results of randomised studies were combined using meta-analytic techniques. Papers were categorised according to study design, reflecting susceptibility to bias. Questions were answered using the best evidence available. When considering a question of the effect of an intervention, if the question could be answered by category I evidence provided by a meta-analysis or randomised controlled trial, then studies of weaker design (controlled studies without randomisation) were not reviewed. Where studies were of poor quality, or contained patient groups considered a priori likely to have different responses, the effects of inclusion or exclusion were examined in sensitivity analyses. No trials that met the inclusion criteria were excluded from the primary analyses. However, where data on relevant outcomes included were not available, these studies could not be incorporated, thus leading to the potential for publication bias.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations were graded A to D as shown below. The guideline distinguishes between the category of evidence and the strength of the associated recommendation. It is possible to have methodologically sound (category I) evidence about an area of practice that is clinically irrelevant or has such a small effect that it is of little practical importance and would attract a lower strength of recommendation. More commonly, a statement of evidence would only cover one part of an area in which a recommendation has to be made or would cover it in a way that conflicts with other evidence. In order to produce comprehensive recommendations, the group had to extrapolate from the available evidence. This may lead to weaker levels of recommendation (B, C or D) based upon evidence category I statements. It is not assumed that guideline group members will always be able to reach agreement on the interpretation of research evidence, and the nature of such disagreement is reflected in the text of the guideline.

Strength of recommendations:

A: Directly based on category I evidence (meta-analysis of randomised controlled trials or at least one randomised controlled trial)

B: Directly based on category II evidence (at least one controlled study without randomisation or one other type of quasi-experimental study) or extrapolated recommendation from category I evidence

C: Directly based on category III evidence (non-experimental descriptive studies) or extrapolated recommendation from category I or II evidence

D: Directly based on category IV evidence (expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence

COST ANALYSIS

This guideline involves a systematic appraisal of effectiveness, compliance, quality-of-life, safety and health service resource use and costs of a medical intervention provided in the British health care setting. These being the most current, pertinent and complete data available, the economic analysis attempts a robust presentation showing the possible bounds of cost-effectiveness that may result. The range of values used to generate cost-effectiveness estimates reflects the available evidence and the concerns of the guideline development group. Recommendations are graded reflecting the certainty with which the costs and consequences of a medical intervention can be assessed.

All drugs included in major trials have been costed. Drug treatments for patients with previous myocardial infarction and previous myocardial infarction with heart failure were costed using the dosing schedules found in the trials. Assuming a common class effect for the effectiveness and tolerability of drugs, the cheapest (based on comparative costs as of November 1999) are shown in Table 3 titled "Comparative Cost of Drug Treatments for Patients with Previous Myocardial Infarction" (see the original guideline document). It is recognised that there is a potential impact on compliance when trading-off cost and frequency of dosing; this is reflected by showing the cheapest once or twice daily dose where this is more expensive than a cheaper but more frequent dose requirement.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline development group was composed of four types of members: relevant health care professionals; a patient/carer representative; specialist resources; and a specialist small-group leader.

The research team consisted of the specialist resources (Nick Freemantle and James Mason) and the development group leader (Martin Eccles). The specialist resources were a health services researcher and a health economist. The research team was responsible for reviewing and summarising the literature on clinical effectiveness, safety, quality of life and health economics and feeding this information back to the group. The group leader had the role of ensuring that the group worked effectively. The research team was responsible for the drafting of the guideline and the resourcing of the guideline development group.

Recommendations were graded according to a rating scheme (scheme given). The guideline distinguishes between the category of evidence and the strength of the associated recommendation. At times in order to produce comprehensive recommendations, the group had to extrapolate from the available evidence. This may lead to weaker levels of recommendation (B, C or D) based upon evidence category I statements. It is not assumed that guideline group members will always be able to reach agreement on the interpretation of research evidence, and the nature of such disagreement is reflected in the text of the guideline.

It was accepted that there would be areas without evidence where recommendations had to be made and that consensus would be required to deal with these areas. Where this process identified important unanswered research questions, these were recorded at the end of the relevant section of the guideline.

The guideline was also reviewed externally by a consultant cardiologist, whose comments had scope to influence the style and content of the guideline. However, the guideline remains the responsibility of the development group.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

All recommendations are for patients who have survived a myocardial infarction and are made with the aim of decreasing subsequent premature mortality. Recommendations for drug treatment are made assuming that clinicians will take account of both patient tolerability and compliance and the indications, contraindications and cautions as listed in the British National Formulary (BNF) or Summary of Product Characteristics. Within three of the drug groups discussed in this guideline (beta-blockers, angiotensin-converting enzyme [ACE] inhibitors, statins) not all drugs have a licence for the indications discussed in the guideline. To achieve the benefits described within this guideline, drugs should be used in dosages as close as possible to those used in the trials described.

In reaching treatment decisions clinicians will need to appropriately share the information within the guideline to allow patients to be appropriately informed about, and involved in, decision making about their care.

Strength of recommendations (A through D) ratings are defined at the end of the "Major Recommendations" field.

Drug Treatment

Patients With Prior Myocardial Infarction Who Do Not Have Heart Failure

Which drugs?

- All patients should be offered long term treatment firstly with a beta-blocker and an antiplatelet drug (aspirin), and then with a statin and an angiotensin-converting enzyme inhibitor. This sequencing of initiation reflects the evidence from trials and estimates of cost-effectiveness (A). Not all

angiotensin-converting enzyme inhibitors or statins have a licence for this indication.

- The precise lower limit of the level of cholesterol that should be treated is unclear. Across the statin trials considered, the lower limit of the range of cholesterol values defining entry into the trials varied; one large trial enrolled patients with serum cholesterols down to 4 mmol/l. Licence indications currently suggest a lower limit of 4.8 mmol/l or 5.5 mmol/l depending on the drug used. (D).
- Beta-blockers and angiotensin-converting enzyme inhibitors will also be considered for the management of symptoms (e.g. in stable angina) or risk factors (e.g. hypertension) (D).
- Calcium channel blockers, nitrates, and potassium channel activators have no effect on premature mortality making their role the management of symptoms and risk factors (principally hypertension) (A). They should therefore only be used in those patients who are intolerant of beta-blockers and angiotensin-converting enzyme inhibitors (D). Given their effect on non-fatal myocardial infarction, verapamil or diltiazem should then be considered initially (B). Subsequent necessary treatment with other calcium channel blockers, nitrates or potassium channel activators is then appropriate (D).

When to start drug treatment

- The recommended starting points for drug treatments are based on the initiation points in the clinical trials.
- Beta-blockers, antiplatelet drugs (aspirin) and angiotensin-converting enzyme inhibitors should be initiated whilst patients are in hospital as there is evidence to support benefit following early initiation. If this does not happen then primary care clinicians should initiate them as soon after discharge as possible (A).
- Although there is no evidence of the long-term benefit from the use of statins initiated prior to 12 weeks post-infarct, many patients will have been taking statins prior to admission or will have them initiated in hospital. All patients discharged from hospital who are not already taking a statin should be assessed and have treatment initiated 12 weeks after a myocardial infarction (A).

Monitoring treatment

- Patients being considered for treatment with a statin should have an initial serum cholesterol measurement both to exclude familial lipid disorders and to identify those patients with a serum cholesterol level that does not need treating. Once these have been excluded, further measurement allows an assessment of response to treatment and informs the assessment of compliance with treatment. The frequency of such monitoring is unclear; the U.K. National Health Service National Service Framework for Coronary Heart Disease suggests annually (D).
- Patients being considered for treatment with angiotensin-converting enzyme inhibitors should have their renal function checked prior to initiation and after each significant dose increase (D).

Continuation of treatment

- Based on the evidence from the trials, treatment should continue long term (D).
- The treatment durations, for which there is at least one trial that provides direct support, are three and a half years for antiplatelet drugs (aspirin), four years for beta-blockers and angiotensin-converting enzyme inhibitors and six years for statins. In the absence of a clear reason to stop treatment it seems reasonable to continue treatment indefinitely (D).

Patients With Prior Myocardial Infarction Who Have Diabetes

- There is evidence that intensive insulin therapy initiated soon after admission for acute myocardial infarction reduces mortality (B). To achieve the benefits demonstrated in the single trial in this area involves 4 daily insulin injections continuing for at least three months (B).

Patients With Prior Myocardial Infarction and Heart Failure

- Patients with prior myocardial infarction and heart failure are a relatively ill group of patients and care is required when initiating drug treatments (D).
- All patients should be offered long-term treatment with an angiotensin-converting enzyme inhibitor and then a beta-blocker (not all beta-blockers have a license for this indication). In addition they should be treated with an antiplatelet drug (aspirin). Patients who have moderate or severe heart failure (New York Heart Association [NYHA] grade 3 or 4) should be treated with spironolactone. All of these treatments are cost effective (A).
- Patients are likely to continue to need symptomatic treatment with a loop diuretic (D). In patients with mild symptoms of heart failure (New York Heart Association grade 1 or 2) it is unclear whether spironolactone decreases premature mortality. It may represent a reasonable choice of adjuvant symptomatic therapy (D).
- As patients with heart failure were almost always excluded from trials there is no evidence on which to recommend the use of statins in such patients. Statin use will be influenced by clinical and practical considerations, such as whether patients were treated with them prior to developing heart failure (D).

When to start drug treatment

- The recommended starting points for drug treatments are based on the initiation points in the trials.
- Angiotensin-converting enzyme inhibitors and antiplatelet drugs (aspirin) should be initiated whilst patients are in hospital as there is evidence to support benefit following early initiation. If this does not happen then primary care clinicians should initiate them as soon after discharge as possible (A).
- Beta-blockers can be initiated at any point. Treatment should start with low doses and should be slowly increased, for example at fortnightly intervals, over a period of up to 12 weeks (A).
- Given the limited experience initiating beta-blockers it is currently unclear whether this can be done safely in primary care. Whilst the British National Formulary recommends hospital supervision it seems possible that there are a group of patients with heart failure for whom general practitioners (based on their knowledge of the patient´s clinical condition) may feel able to initiate treatment in primary care. Unfortunately the characteristics of this patient

group are not currently clear. Discussion at a local level may inform appropriate methods of treatment initiation (D).
- Spironolactone can be initiated at any point. In patients with moderate to severe symptoms of heart failure (New York Heart Association grade 3 or 4), given the time involved in achieving full dosages of beta-blockers, it seems reasonable to consider initiating spironolactone before beta-blockers (D).

Monitoring treatment

- Patients being considered for treatment with angiotensin-converting enzyme inhibitors should have their renal function checked prior to initiation and after each significant dose increase (D).
- Patients being treated with spironolactone should have their serum potassium monitored (D).

Continuation of treatment

- Based on the evidence from the trials, treatment should continue long term (D). The treatment durations, for which there is at least one trial that provides direct support, are three and a half years for angiotensin-converting enzyme inhibitors, two and a half years for beta-blockers and two years for spironolactone. In the absence of a clear reason to stop treatment it seems reasonable to continue treatment indefinitely (D).

Non-drug Treatment

Rehabilitation

- Patients should be offered enrolment in a rehabilitation programme that has a prominent exercise component within it (A). Although many of the trials imposed upper age limits for recruitment, the guideline development group felt that in a service setting it was more appropriate to be guided by functional ability and patient preference (D).

Diet

- Given the nature of the available evidence of the effectiveness of dietary manipulation as a strategy for secondary prophylaxis it is not possible to recommend specific dietary manipulation (B).

Definitions:

Strength of recommendations:

A: Directly based on category I evidence (meta-analysis of randomised controlled trials or at least one randomised controlled trial)

B: Directly based on category II evidence (at least one controlled study without randomisation or one other type of quasi-experimental study) or extrapolated recommendation from category I evidence

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D: Directly based on category IV evidence (expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Statins

- Based on the data from randomised controlled trials in 1,000 patients who have experienced a myocardial infarction, treatment with statins for a year will avoid about four deaths, six non-fatal myocardial infarctions and two strokes. These benefits appear similar regardless of initial cholesterol level.

Beta-blockers

- Based on the data from randomised controlled trials, in 1,000 unselected patients who have experienced a myocardial infarction, treatment with a beta-blocker for a year will avoid about thirteen deaths and eight non-fatal myocardial infractions.
- Potential benefits from beta-blockers may be achieved through early initiation of therapy. However, these will continue to accrue over long-term use.

Angiotensin-converting enzyme inhibitors

- Angiotensin-converting enzyme inhibitors are associated with a small reduction in mortality in short-term use immediately after acute myocardial infarction. Based on the data from randomised controlled trials, in 1,000 patients who have experienced a myocardial infarction, treatment with an angiotensin-converting enzyme inhibitor for a year will avoid about two deaths.
- In longer-term use in patients at raised cardiovascular risk, Angiotensin-converting enzyme inhibitors are associated with a moderate reduction in mortality. Based on one large randomised controlled trial, if 1,000 patients are treated for one year 4 deaths will be avoided.

- Long term treatment with angiotensin-converting enzyme inhibitors is associated with a substantial reduction in all cause mortality in selected patients with signs of heart failure who have recently experienced an myocardial infarction. Based on the data from randomised controlled trials treating 1,000 patients with heart failure with angiotensin-converting enzyme inhibitors for a year, commencing soon after an index myocardial infarction, will avoid 18 deaths).
- Angiotensin-converting enzyme inhibitors may also reduce the incidence of non-fatal myocardial infarction in patients with prior myocardial infarction and heart failure.
- Long term treatment with angiotensin-converting enzyme inhibitors is associated with a substantial reduction in all cause mortality in patients with symptoms of heart failure and reduced left ventricular function who may or may not have experienced an myocardial infarction. Based on the data from randomised controlled trials treating 1,000 patients for one year will avoid about 15 deaths.

Angiotensin-converting enzyme inhibitors and beta-blockers combination therapy

- Beta-blockers are associated with a substantial reduction in all cause mortality in patients with symptoms of heart failure being treated with an angiotensin-converting enzyme inhibitor, who may or may not have experienced a myocardial infarction. Based on the data from randomised controlled trials treating 1,000 patients with heart failure for one year with beta-blockers will avoid 35 deaths

Spironolactone

- Spironolactone is associated with a decrease in all cause mortality among patients with moderate to severe heart failure treated optimally with angiotensin-converting enzyme inhibitors.

Antiplatelet therapy

- Antiplatelet therapy is associated with a reduction in all cause mortality and non-fatal myocardial infarction in patients who have experienced a previous myocardial infarction.

Insulin glucose infusion followed by subcutaneous insulin

- There is evidence that rigorous control of diabetes post myocardial infarction lowers mortality. Based on the results of one trial, if 1000 patients where treated with this intervention for one year, 30 deaths would be avoided.

Cardiac rehabilitation

- There is good evidence that cardiac rehabilitation that includes an exercise component is associated with a reduction in mortality and major morbidity in patients post myocardial infarction.
- Based on the data from randomised controlled trials if 1,000 patients were treated with cardiac rehabilitation commencing soon after myocardial

infarction, and followed up for between 3 months and 5 years, 24 deaths will be avoided.

Mediterranean diet

- Dietary changes in line with a Mediterranean type diet (in particular the avoidance of meat and dairy products and an increase in the consumption of fatty fish) appear to reduce mortality. Based on the data from randomised controlled trials implementing dietary advice on Mediterranean Diet for 1,000 people for one year would lead to the avoidance of 18 deaths. This finding is in line with evidence that describes the effect of therapeutic doses of poly-unsaturated fatty acids.

Subgroups Most Likely to Benefit:

Patients who develop heart failure following a myocardial infarction and patients who have diabetes

POTENTIAL HARMS

Side effects of recommended drug treatments

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The development group assumes that health care professionals will use general medical knowledge and clinical judgment in applying the general principles and specific recommendations of this document to the management of individual patients. Recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in the light of circumstances presented by individual patients and available resources. In reaching treatment decisions clinicians will need to appropriately share the information within the guideline to allow patients to be appropriately informed about, and involved in, decision making about their care.

Within this guideline the authors have (in the appendices) reported the diagnostic criteria used in studies included in their review to allow clinicians to judge how closely these apply to the individual patients whom they will manage.

This guideline is concordant with the U.K. National Health Service (NHS) National Service Framework for Coronary Heart Disease, which provides the general framework for the monitoring of patients with coronary heart disease. This guideline provides a firm evidence base for clinical actions and for the principles of relevant audit criteria within the National Service Framework. By its nature, the National Service Framework specifies the audit criteria to a greater level of detail than the guideline. The recommendations within the guideline differ from the content of the National Service Framework only in the area of initiating statins where the guideline offers recommendations based strictly on the evidence.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This guideline is published as part of a range of clinical resources to support the U.K. National Health Service (NHS) National Service Framework for Coronary Heart Disease. Its implementation should take place as part of the health improvement plans for each local health economy.

- Local health communities will need to review existing service provision against this guidance. This review should result in an implementation strategy which will identify the resources required to implement fully the recommendations set out in the guidelines, the people and processes involved and the timeline over which full implementation is envisaged.
- Relevant local clinical guidelines and protocols should be reviewed in light of this guidance and revised accordingly.
- To enable clinicians to audit their own compliance with this guideline it is recommended that, if not already in place, management plans are recorded for each patient who has suffered a myocardial infarction.
- The audit criteria can be used to support the evaluation of clinical practice and continuous improvement in the management of patients following a myocardial infarction. These six criteria are suitable for use in primary care and are concordant with those within the Coronary Heart Disease National Service Framework.
- The baseline population is those patients discharged from hospital having survived a myocardial infarction. The audit criteria require the identification of a sub-set of patients with heart failure:
    1. Number (and %) of all patients with and without heart failure appropriately taking beta-blockers
    2. Number (and %) of all patients with and without heart failure appropriately taking aspirin
    3. Number (and %) of all patients with and without heart failure appropriately taking a statin (taking account of serum cholesterol level)
    4. Number (and %) of patients with and without* heart failure appropriately taking an angiotensin-converting enzyme inhibitor
    5. Number (and %) of patients with heart failure appropriately taking spironolactone
    6. Number (and %) of all patients (i) offered and (ii) enrolled into a rehabilitation programme

  * This criterion is not directly concordant with the Coronary Heart Disease National Service Framework due to evidence that has emerged since the National Service Framework was written.

- This information should be incorporated into local clinical audit data recording systems and consideration given (if not already in place) to the establishment of appropriate categories in electronic record systems
- Prospective clinical audit programmes should record the proportion of treatments adhering to the guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's

formal clinical governance arrangements and where they are linked to specific post-graduate activities.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Newcastle upon Tyne, Center for Health Services Research, University of York, Centre for Health Economics, Medicines Evaluation Group. Prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation and dietary manipulation. Newcastle upon Tyne (UK): University of Newcastle upon Tyne, Centre for Health Services Research; 2001 Apr. 115 p. [289 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Apr 23

GUIDELINE DEVELOPER(S)

University of Newcastle upon Tyne, Centre for Health Services Research - Academic Institution
University of York, Centre for Health Economics, Medicines Evaluation Group - Academic Institution

SOURCE(S) OF FUNDING

Supported by funding from the Department of Health of England and Wales.

GUIDELINE COMMITTEE

Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: John Cleland; Martin Eccles; Nick Freemantle; Eve Knight; Keith MacDermott; James Mason; Basil Penney; Colin Pollock; Wendy Ross; Jane Skinner; Malcolm Thomas

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following members of the guideline development group have declared no competing interests in relation to the guideline. Martin Eccles, Eve Knight, Keith MacDermott, Basil Penney, Malcolm Thomas.

The following competing interests were declared.

John Cleland has received honorariums and money for research from a number of companies who make beta-blockers and ACE inhibitors. He is about to embark upon a study funded by the Veterans Administration comparing Warfarin, Aspirin and Clopidogrel in patients with Heart Failure and is on the Steering Committee of this study.

Nick Freemantle has held an unrestricted grant from SmithKline Beecham to investigate the effectiveness of beta-blockers in secondary prevention. He is advising Servier Laboratories on the design and conduct of a randomised trial of ACE inhibitors in elderly people with diastolic heart failure. He holds a grant from Servier Laboratories for data management and analysis of a large European survey on the treatment of heart failure. He holds a grant from Orion Pharma/Abbott Pharmaceuticals, who have an investigational inotropic agent. Has held a number of grants from the Department of Health on the investigation of cardiovascular drugs and their implementation in practice.

James Mason has worked for several companies who manufacture drugs for cardiovascular disease, either as an invited speaker or consultant. None of the work was in the field of cardiovascular disease. Has been involved in a variety of projects funded by the Department of Health.

Colin Pollock has been involved on a paid consultancy basis on an NHS Advisory Panel for Janssen-Cilag. Has also, on an ad hoc consultancy basis, provided advice to Ted Butler Associates which is an independent healthcare research company which often works with most major pharmaceutical industry companies in the UK.

Wendy Ross is a member of the Newcastle & North Tyneside District Drug & Therapeutics Committee, which is responsible for developing the district formulary.

Jane Skinner has received a fee from a journal to write a review of post MI care.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available (in Portable Document Format [PDF] format) from the National Institute for Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- NICE guideline on prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation, and dietary manipulation. London: National Institute for Clinical Excellence (NICE), 2001 Apr. 12 p.

Electronic copies: Available from the NICE Web site:

- HTML format
- Portable Document Format (PDF)

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: 23652. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Treatments following a heart attack. Information for patients. In: NICE guideline on prophylaxis for patients who have experienced a myocardial infarction: drug treatment, cardiac rehabilitation, and dietary manipulation (Appendix C). London: National Institute for Clinical Excellence (NICE), 2001 Apr. pp. 10-12.

Electronic copies: Available from the NICE Web site:

- HTML format
- Portable Document Format (PDF)

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455 (quote reference number 23653 for the English version and 23654 for the English/Welsh version); postal address: 11 Strand, London, WC2N 5HR.

NGC STATUS

This summary was completed by ECRI on January 24, 2002.

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